UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ENDO PHARMACEUTICALS, INC.,

Plaintiff,

v. 12 CV 8985 (TPG)

ACTAVIS INC.,

Defendant.

ENDO PHARMACEUTICALS, INC.,

Plaintiff,

v. 13 CV 3288 (TPG)

ROXANE LABORATORIES,

Defendant.

New York, N.Y.
August 26, 2013
2:45 p.m.

Before:

HON. THOMAS P. GRIESA,

District Judge

APPEARANCES

DECHERT LLP
Attorneys for Plaintiff
ROBERT D. RHOAD, ESQ.
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(Case called)

(In open court)

THE DEPUTY CLERK: Case of Endo Pharmaceuticals v. Actavis Inc. and Roxane Laboratories.

THE COURT: All right, what do we need to do today?

MR. BLACK: Thank you, your Honor. Martin Black for Endo. We really have two issues. The overall issue is setting a schedule for the disposition of the preliminary injunction motion that we filed to maintain the status quo pending trial. Actavis and Roxane have obtained FDA approval and have the ability therefore to launch a generic product before the trial would be held. We had presaged this issue at the conference we had back in June, I guess it was, and we filed our papers and the parties are cooperating on discovery, but we all thought that it would be beneficial to get a date certain for a hearing and take your Honor's pleasure on how such a process should unfold when the hearing would take place.

THE COURT: When you talk about a preliminary injunction hearing and a trial, why would you have both of them?

MR. BLACK: The preliminary injunction hearing would be obviously for maintaining the status quo until there's a --

THE COURT: Usually a preliminary injunction hearing gets pretty deeply into the thing.

MR. BLACK: It does, your Honor, and obviously it's

somewhat abbreviated compared to a full trial. But the difficulty we have is that the defendants are insisting on their right to launch the product before the Court can have a full trial, which would take some time. These cases are in the very early discovery stages.

THE COURT: A little louder, please?

MR. BLACK: I'm sorry. These cases were filed a little earlier this year. We just worked out the protective order. Discovery has just begun. I don't think the parties are prepared for a full trial on the merits. Our purpose in bringing the motion is to preserve the status quo pending a trial. Defendants are not agreeable to that, and therefore we have no choice but to bring a preliminary injunction motion.

THE COURT: What are the issues to be dealt with at the motion or the trial?

MR. BLACK: For a preliminary injunction we would need to establish the plaintiff's infringement and irreparable harm. We bear those burdens.

THE COURT: I know. But that's generalities. What are the specific issues here?

MR. BLACK: Okay. The specific issues on infringement, doesn't look like there's going to be any. Looks like infringement is not going to be disputed. They're disputing the validity of the patents. They're disputing that if they launch into the market it will be irreparable harm to

Endo. Our view is when a generic launches against a branded company that the eggs are cooked and it's impossible to unscramble them.

THE COURT: What are the issues about validity?

MR. BLACK: On validity we believe there really isn't a serious issue, your Honor. Two of the patents were --

THE COURT: You believe what?

MR. BLACK: I don't believe there's a serious issue. Two of the patents -- they will disagree, of course, but two of the patents have already been to the Federal Circuit. One of the patents, the Patent Office -- I'm sorry, am I too far away?

THE COURT: Why don't you sit down? These are very awkward microphone arrangements. I'll hear you better.

MR. BLACK: Thank you, your Honor. Two of the patents are from a family which was issued recently and the validity of those patents was debated in the Patent Office and went up to the Federal Circuit which ruled in our favor so we have a Federal Circuit decision affirming the validity of one of the patents and then shortly after that a related patent in the same family issued as well. There's a third patent which is --

THE COURT: Patent for what -- what are you patenting?

MR. BLACK: Sure, your Honor. The product at issue in this case is an opioid. It's called oxymorphone. It's similar to OxyContin. It's a strong narcotic available only by prescription and it's a Schedule II controlled substance.

There was an original round of cases relating to this product. Endo then came up with an approved product which is a crush-resistant formulation. One of the issues which these products, like oxymorphone and oxycodone, is that they are attractive to drug abusers. They can be purchased, crushed and then snorted and the industry has been working on ways to provide safer products to the public.

Endo came up with a crush-resistant formulation, launched that product and then removed the earlier crushable version from the market. The patents at issue cover, in this proceeding, cover two things. One is the dissolution rates and pharmacokinetic characteristics, that is, how the drug gets distributed in the blood and what the effect is on the patient and the third one is a patent relating to impurities. There's a cancer-causing product in oxymorphone generally and there are ways of getting rid of the cancerous impurity and the patent relates to that.

Those are the basic issues related to the patents. There are, of course, going to be issues relating to irreparable harm and Actavis has raised an issue of license relating to the prior litigation and whether they have expressly or impliedly obtained rights to the patents not listed in the agreement.

THE COURT: What went before the Federal Circuit?

MR. BLACK: There was a prosecution going on in the

Patent Office of one of the Endo patents that is at issue here.

THE COURT: Which Endo patent?

MR. BLACK: The patent was -- there's two patents. I want to make sure I give you the right number. It's the '122 patent which relates to the pharmacokinetic characteristics.

THE COURT: '122 patent is about what?

MR. BLACK: It's about the way in which the product, for want of a better word, dissolves in the blood and how long it remains active in the body.

THE COURT: That's the '122 patent.

MR. BLACK: It might be better -- it's an extended release formulation as opposed to -- many drugs you take them, they have a half life, they go out of the body, are no longer effective within a couple of hours. There are ways to make them last for longer periods of time. That's the practical impact of the drug.

THE COURT: And what is the other patent?

MR. BLACK: The related patent to the '122 is the '216. They have very similar claims and they're from the same family, and then the third patent I mentioned about the removing impurities from the patent, from the oxymorphone is the '482.

THE COURT: Removing --

MR. BLACK: It covers a version of oxymorphone with a low, it's called a low abuk, a-b-u-k, an impurity which has

been found to cause cancer.

THE COURT: So it's about the removing impurities or a low level of impurities?

MR. BLACK: Low level of impurities. It's a compound which has a very low level of impurities and the patent describes how to make so-called low abuk oxymorphone.

THE COURT: And all these things are about oxymorphone?

MR. BLACK: Yes.

THE COURT: And that's your client's product?

MR. BLACK: Yes.

THE COURT: How do you spell that?

MR. BLACK: O-x-y-m-o-r-p-h-o-n-e.

THE COURT: Now, what happened in the Federal Circuit?

MR. BLACK: The Patent Office did not grant the patent application that Endo had filed. Endo appealed to the Federal Circuit from the Patent Office decision and the Patent Office, the Federal Circuit overturned the Patent Office decision and concluded that the Patent Office erred in failing to issue the patent.

In front of the Patent Office and the Federal Circuit at that time was a tremendous amount of prior art that had come to the surface during prior litigation and we doubt that there are going to be any new issues.

THE COURT: What do you mean prior litigation?

MR. BLACK: There was prior litigation with some of the defendants in this case on the early non-crush -- the crushable product which we've taken off the market and there was litigation over that product and during the course of that litigation the defendants raised a lot of prior art, all of which Endo provided to the Patent Office and still obtained the '122 and '216 patents.

THE COURT: Well, I don't -- then what are the issues to be heard at a preliminary injunction hearing?

MR. BLACK: At the moment there are -- at the moment the defendants are -- Roxane is not selling this product, although they have recently obtained FDA approval and can do so, unless there's a court order or an agreement to maintain the status quo during trial. Actavis has been selling two small dosage strengths which have virtually no market share but they now would like to expand into dosage strengths which are the big sellers and would cause serious harm.

THE COURT: What products are they selling?

MR. BLACK: They want to sell the original crushable oxymorphone product.

THE COURT: Who wants to do that? Both defendants?

MR. BLACK: Correct.

THE COURT: So the defendants want to sell what?

MR. BLACK: Call it crushable oxymorphone. Generic versions of the crushable oxymorphone.

THE COURT: Do I have this right? They want to sell a crushable version of oxymorphone.

MR. BLACK: Correct.

THE COURT: Both defendants want to do that.

MR. BLACK: Correct.

THE COURT: So what is there to be heard at a preliminary injunction hearing?

MR. BLACK: The questions would be whether or not given the four-factor test of likelihood of success on the merits, irreparable harm, public interest and potential harm to the defendants, whether the factors balance in favor of issuing a preliminary injunction that would maintain the status quo --

THE COURT: Look. Please don't give me those topics. What are the specific factual issues to be dealt with at preliminary injunction hearing?

MR. BLACK: Whether they have raised a sufficient issue of validity on the patents to defeat our claim for relief. We only received their papers a couple of hours ago, so I'm not in a position to really go through what pieces of prior art they're referring to or not. But that's the issue. That's the issue.

THE COURT: In other words, the preliminary injunction, the validity depends on prior art, right?

MR. BLACK: Right. There's an issue with Actavis about whether they have a license which would give them the

right to sell, and then there's the issue of irreparable harm which turns primarily on what the impact would be on the marketplace and whether we can put the eggs back together after they've been broken and scrambled and after a trial if the plaintiff were to prevail.

THE COURT: Okay. What do the defense say are the issues to be heard at the preliminary injunction hearing?

MR. WEISS: Thank you, your Honor. Just out of habit maybe I'll just stand up and then sit down. It's Charles Weiss, W-e-i-s-s, for Actavis.

THE COURT: Okay.

MR. WEISS: Mr. Black has identified the legal standards and if the Court would indulge me I would get into some of the specific facts that are presented here and the specific legal issues.

THE COURT: Okay.

MR. WEISS: I'm going to start with the prior litigation. So Endo sued Actavis in the District of New Jersey in 2008 on the exact product that is the subject of this case. The Court knows that a generic company that wants to sell files an ANDA, the abbreviated new drug application. Actavis filed its ANDA in 2008, as did many other companies, including Roxane represented by my colleagues behind me, Watson Barr, which is now Teva; Sandoz, which is part of Novartis, Mallinckrodt -- I may have missed one. In any event, Endo settled with everyone

in 2009 including my client Actavis. They granted Actavis a license and a covenant not to sue on the patents that were in that litigation and related patents. Under that license Actavis entered the market with two of its strengths, which Mr. Black referred to, this is the 7.5-milligram and the 15-milligram, in June 2011. That's when we were licensed to enter on those strengths. Everyone else was licensed to enter in 2013, and Impax in fact entered and began selling all the other strengths, this is 5, 10, 20, 30, 40 and so on, in January 2013. We were allowed to sell beginning 2013 also and we got our final approval from FDA in June, or perhaps July. In any event, this summer of 2013. And we want to sell the other strengths of the product that we're already selling, and that we are licensed to sell.

Now, there's no dispute that it's the same product. They pled that it's the same product in their complaint. The license issue is where Endo says well, wait a minute, after we settled that lawsuit we continued prosecution and we got two more patents and even though we licensed you, you're not able to practice your license and essentially they're saying the consideration was illusory. So Endo bargained to keep Actavis off the market until 2013 in settlement of that case. They got certainty. Both sides avoided the risk. Endo avoided the risk that the patents would be held invalid or non-infringed and that Actavis would launch in 2009 or 2010. And Actavis of

course avoided the risk that it would lose entirely and would be enjoined until the patents expired. Typical settlement of a patent infringement case or any other civil case.

Here we are in 2013 with Endo saying --

THE COURT: You're saying that the issue of validity was settled?

MR. WEISS: Not as to these patents, your Honor, no.

THE COURT: Not as to what?

MR. WEISS: Not as to the patents that Endo is asserting now. But all of the patents are licensed. Valid or not, it doesn't matter, they're licensed. And so here we are in 2013 with a license that says you're allowed to enter with the other strengths in 2013 and Endo is saying you can't enter in 2013 because we got new patents. Now, Endo's position is those patents are not within the scope of the license. That is primarily, if not exclusively, a legal issue. It is four or five pages of our brief. It is one document which is the license agreement which is in front of the Court and it is very nicely captured in a single Federal Circuit decision which is in our brief also, I have copies to hand out if the Court wants, it's TransCore LP v. Electronic Transaction Consultants Corp., 563 F.3d 1271, Federal Circuit 2009, dead on factually to this case. Settlement of an earlier litigation, grant of a license and covenant not to sue, a new patent issues to the patent owner, the patent owner says nope, you can't sell the

product that was licensed, summary judgment by the district court in favor of the accused infringer who had the license, affirmed by the Federal Circuit as a matter of law. A licensor cannot pull the rug out from under its licensee on the exact product.

Now, we only brought our papers in this morning so obviously the Court has not had a chance to look at them, but that is the license issue. We could easily file tomorrow a four-page summary judgment brief on that and motion. That is the license issue.

The validity issue is --

THE COURT: I don't understand what is the license issue? There are new patents, right?

MR. WEISS: Yes, your Honor.

THE COURT: And can't they claim -- don't they have rights under their new patents? I just don't understand what you've gone into.

MR. WEISS: Of course, your Honor. They have rights, but among the things that a patent owner can do is grant licenses. And the law says when you settle a litigation and grant a license for a product, which is what happened in 2009 in settlement of the District of New Jersey case, you cannot come back years later when you've gotten a new patent and say that the exact product that you licensed can't be sold because it infringes. It's an illegal estoppel. And that is --

THE COURT: The crucial thing I think you're saying is the exact product.

MR. WEISS: Correct. And I can answer that, your Honor. So the licensed product was defined in the license agreement as -- and the license agreement is in the papers we delivered. I can hand up extras if your Honor wants. It was defined as the Opana ER generic product, which means any product that is marketed and/or sold under the Actavis ANDA. That's a defined term also. Actavis ANDA says -- ANDA number 79-046 and any amendments or supplements thereto -- the remaining strengths of the same product that are at issue now on this preliminary injunction and this lawsuit come from this exact ANDA by number, and that is actually pled, correctly so, by Endo. Now, Endo says the patents that we're asserting here are not licensed, but it does not dispute that the product at issue before the Court is otherwise licensed. And then we get into the estoppel issue which is addressed in the TransCore case that I cited.

Now, I don't think that there is parol evidence that would negate this, but I don't know, and as Mr. Black said as I acknowledge we only delivered our papers this morning. But this is a straightforward issue that is separate and apart from potentially complicated issues of patent validity.

Now, on the issue of patent validity Mr. Black said that there was an adjudication by the Federal Circuit. He then

clarified -- and I think this is very important so I'm going to repeat it. This was part of ex parte prosecution. This was Endo v. the examiner. This was not litigated, these patents were not litigated and the issue in front of the Patent Office was the extent to which the experience with other narcotics could be applied to oxymorphone. So as Mr. Black mentioned oxymorphone is a narcotic pain killer. Products were already on the market, extended release narcotic painkillers; MS Contin, which is morphine, OxyContin, which is oxycodone, same family of molecules, all opiates, all going from immediate release to sustained release. The claims were rejected by the post office and the examiner had in front of him only some information about the products that were out there.

So what Endo said was, well, you can't equivalently make oxycodone and oxymorphone because they have different half lives, but MS Contin wasn't there, and MS Contin morphine has almost the same half life as oxymorphone. And similarly, they said, well, the dissolution testing in the prior art was paddles v. baskets and you don't know how they match up.

Well, this is a real simple issue. Dissolution testing, you have a beaker with fluid in it --

THE COURT: What you're saying is there was prior art which makes what their new patents invalid or what?

MR. WEISS: Yes, your Honor. And I can explain it --

THE COURT: And the patents that were at issue on the

license, are you saying those are invalid too?

MR. WEISS: No. There's no dispute we're licensed under those, those patents are licensed in this lawsuit.

THE COURT: It's the new patents.

MR. WEISS: Yes, your Honor.

THE COURT: Prior art.

MR. WEISS: And there's also a 112 defense, but if I could have a moment to finish the prior art if the Court would indulge me.

THE COURT: Sure.

MR. WEISS: The claims at issue go to how fast the claims dissolve in a beaker. This is a common test for extended release drugs. You take a beaker on the lab bench, you fill it with fluid, you put the tablets in and you stir it and you can stir it either with paddles, it looks like a fan sort of, or you can put the tablets in a little basket and spin the basket. And so one is called a paddle method and one is called a basket method. And the data that the patent examiner had that he was relying on was basket method. One of their claims say paddle method.

Endo says, well, we don't have the information, Mr. Examiner, for you to extrapolate from one to the other. Well, we have the information. It's in the Hanson handbook that's attached to Dr. Kibbe's declaration, it's explained in Dr. Kibbe's declaration and what Dr. Kibbe did in his

declaration is simply show how the dissolution rate of the prior art products and patents, MS Contin itself falls right within the ranges that Endo claims, including within the ranges in the previous patent that was litigated against us. That's prior art.

So it all comes together. And I have extra copies if the Court wants to see how the charts look. What I'm holding up is from the Kibbe declaration starting at page 41. So that's the prior art issue.

The Section 112 issue, something I know the Court has some familiarity with, the first patent trial I did was in front of your Honor on human growth hormone, and the patent claims here are directed to every formulation that dissolved at a certain speed. It doesn't matter how you make it. It doesn't matter if it's made with coating, or a matrix or beads or osmotic pump, or gum, it doesn't matter. Anything that works, anything that dissolves at that rate they claim. That was certainly not in front of the Court before, an ex parte prosecution. And the law is very clear that you cannot describe a product structurally, which they did in their specification, they have a couple of examples made with gum, and then claim every other product, no matter how it's made, that does the same thing. And that's discussed in our brief at page 18 and 19.

So factually those are the particular issues that

would be in front of the Court on validity, whether it would be at a preliminary injunction or trial or whether it would be a consolidated proceeding, this is a bench trial, there's no jury. And so factually, those are the particular issues.

There's also this low impurity patent that Mr. Black mentioned which is in a different family. The license issue is the same. There's the estoppel against blocking the very product you've licensed. That patent didn't even come out of Endo. That was done by a British pharmaceutical company and Endo bought it to try to now control the raw material. So we may be developing some interesting defenses down the road about that, but at the moment that's not what we're focusing on. The thing there that's interesting, not disclosed, is that what that English company did, it's called Johnson Matthey, claimed what FDA had already said it was going to set as the standards. So as Mr. Black noted, information developed at this particular impurity, it's called the abuk impurity, A-B-U-K, alpha beta unsaturated ketone, the chemistry doesn't really matter, potentially could damage DNA and materials that potentially damage DNA could potentially cause cancer. Because if the DNA is damaged the cell could possibly become cancerous. That was known around 2002, and FDA contacted manufacturers, contacted stakeholders, said we're going to implement regulations to limit the amount of the abuk impurity. And as the conversations developed FDA said we're going to limit it to ten

parts per million.

After that happened, Johnson Matthey filed a patent application claiming, guess what, abuk was less than 10 parts per million. Interesting fact not in front of the Patent Office.

Now, similarly, another manufacturer and I'm not saying they should be proud of this, another manufacturer did the same thing Johnson Matthey did except they did it nine months sooner. And their application, whether it's valid or not doesn't matter, is prior art to Endo nine months earlier and that is an interference in the Patent Office and the Patent Office has already declared Endo the junior party, meaning that it needs to get behind that application. Now, whether Endo will or will not, at the moment we don't know, but for a preliminary injunction we don't have to know. All we have to know is substantial question of validity and we have it here big time. So factually those are the substantive patent law issues.

As Mr. Black correctly noted for a preliminary injunction there's also the question of irreparable harm. Endo needs to show that by clear and convincing evidence. And, number one, the fact that they demonstrated a willingness in 2009 to license the entire generic industry to enter in 2013 negates irreparable harm as a matter of law. The fact that they got some extra patents later on and changed their mind

does not create irreparable harm.

The other thing which Mr. Black noted, he talked about the crush-resistant product that Endo sells now. Well, that's a separate lawsuit. It's also in front of your Honor. Same cast of characters, but that's not what we're here about today.

THE COURT: Okay. Any other attorney want to talk about the issues?

MR. CLEMONT: Your Honor, Alan Clemont for Roxane. We haven't had a chance to speak up yet.

THE COURT: Go ahead.

MR. CLEMONT: Thank you, your Honor. We're in a somewhat similar position to Actavis, though not quite. The case against Actavis started much earlier. The case against Roxane has just started in June and we filed our answer in mid-July and Endo just a couple of weeks ago filed a reply so we have not, our case has not even really begun.

With regard to whether or not there is the right to a preliminary injunction, Roxane is going to rely on much of the same defenses that Actavis is as well as the irreparable harm issue.

THE COURT: Including the licensing issue?

MR. CLEMONT: With regard to Roxane it's a little bit different than with regard to Actavis. From my understanding of the license agreement that Roxane has we have a slightly broader definition of the license. Our license, because we

were involved in the earlier cases as well, and Roxane settled with Endo then, but as far as Roxane, they also got a license to all patents claiming a common priority with the patents, any patents that Endo would get. What's interesting here, your Honor, is that the two patents, the '122 and the '216 patent claim a common priority to I think it was the '250 patent which was part of the license. So we think we have a little bit stronger of a position on the prior license than what Actavis is saying.

We also have, your Honor, Johnson Matthey, who is the supplier of our active, is a company that Roxane had a supply agreement with before Endo purchased the patent and if you read Endo's preliminary injunction papers against Roxane you'll see that they even say that to the extent that Roxane is purchasing product from Johnson Matthey, they're not going after Roxane on that. There is no grounds for infringement. We have a license there. So we think we have licenses on all the patents.

We also think that the invalidity case here is extremely strong. What happened before the Federal Circuit, and Mr. Weiss was correct, is that it was an appeal from a Patent Office procedure, and what the Federal Circuit said in there is there was a hole in the prior art that the Federal Circuit was looking at and it was whether or not there was this paddle testing of oxymorphone. We have found prior art, not only the Hanson Dissolution Handbook, which equates a 100 rpm

basket to 50 rpm paddles, we have found prior art showing what an extended release oxymorphone product should have for a dissolution profile in a basket. This was not prior art that the Federal Circuit was looking at when they issued that decision. So we think there are very extreme issues with regard to the validity.

With regard to the validity of the '482 we agree with Actavis on the interference issue, that Mallinckrodt as the senior party has priority unless Endo can show differently and that raises a substantial question of patentability. Then when we get to the irreparable harm prong of the preliminary injunction analysis there are at least four factors which we think weigh heavily in the fact that Endo cannot show irreparable harm. One, Endo doesn't even sell this product. They withdrew their NDA. The product that Roxane is trying to bring to market is not a product that Endo sells. Endo permits another manufacturer to be out there selling. They licensed Impax. How are they irreparably harmed if they let someone else on the market?

They also let Actavis on the market with two strengths of the product. How are they irreparably harmed? In order to show irreparable harm you have to show you're not willing to license the patents. They're willing to license the patents.

The other factor I'd like your Honor to consider is Endo previously licensed this product to all the defendants in

the prior New Jersey cases. They said, okay, we have this product. They didn't know they were getting new patents at that time. For all they knew they weren't getting new patents. They said go ahead out on the market generics, here's licenses. You can get out into the market. So I think, your Honor, when you look at this very closely from the irreparable harm standpoint from the -- one other factor, your Honor, on the irreparable harm is Endo itself is being sued for patent infringement on this product by a company called Depomed, so they're not sure they're going to be allowed to market this product.

So, in summary, when you think about it with regard to the two main harms, the irreparable harm and the likelihood of success, Endo can satisfy neither.

THE COURT: Okay. Let me hear, I imagine Mr. Rhoad has something to say.

MR. BLACK: He probably does. I'm going to speak for him, Mr. Black.

THE COURT: Mr. Black. Go ahead.

MR. BLACK: Yes, of course I do. Let's go step by step through the analysis here. First of all, as plaintiff our burden is to show infringement. You didn't hear a word about infringement. That's not on the table. With respect to validity, they bear the burden on clear and convincing evidence. It's not enough for the lawyers to point to some

piece of prior art or make an argument in a courtroom. They have to show by clear and convincing evidence that they have a likelihood of success at trial and we don't believe they can meet that very high burden. In fact, we don't have to do anything other than stand on the issuance of the patent by the Patent Office and here we even have Federal Circuit determination on one of the patents which is highly unusual. So to rule in their favor on validity your Honor would have to consider the clear and convincing evidence standard, the Federal Circuit decision and the evidence before it that the patent is likely to be held invalid and we don't believe they're going to meet that burden.

On irreparable harm --

THE COURT: What about the license issue?

MR. BLACK: Yes, certainly, your Honor. We had prior litigation relating to several patents. That litigation was settled. As is common in litigation of -- with branded and generics, the settlement was in the form of, okay, we will put down our weapons, the patent life that's left on this patent is till a certain date. We'll split the baby and allow you guys to come into the market on a certain date and that's what we did. The three patents that are at issue in this case were not at issue in the prior case.

THE COURT: What they're talking about is product.

MR. BLACK: Yes. That's what's wrong with their

entire analysis. They don't have a license to every patent from the beginning of time till the end of time related to this product. They do not have that kind of license.

THE COURT: Doesn't it depend on what the license says? Does the license use the word product or not?

MR. BLACK: Yes, your Honor, it absolutely depends on what the license says and what the parties' intent was and the surrounding circumstances. They do not have a license on these patents. The agreement does not identify the patents at issue in this case either explicitly or implicitly as licensed patents.

THE COURT: Do the licenses use the word "product"?

MR. BLACK: Yes.

THE COURT: That's what they're talking about is product?

MR. BLACK: Right, but the license is in the form of it says you are licensed to the following patents A, B and C with respect to product X. They did not get a license with respect to patents that were outside the litigation. We settled what was in the litigation. We did not agree to settle or give them a license with respect to things that were not being litigated.

THE COURT: Okay, go ahead.

MR. BLACK: Two of the patents at issue didn't even exist during the litigation, could not have been raised, they

didn't even exist. The third patent was owned by a third party who was uninvolved in the litigation and I'm not even sure when we became aware of it, I think it was probably after the settlement. We purchased that patent. We have a right to assert it. They don't have a license to any of those patents because that's not what the settlement of the litigation was about and the license by its terms does not give them rights in those patents.

THE COURT: What I don't understand is quite from a business standpoint or practical standpoint why we have this litigation. You had an earlier litigation and licenses were granted and I certainly haven't read the licenses and I don't know the terms of the licenses, but there were licenses. And are those licenses still in effect or have they run out or are they still in effect?

MR. BLACK: They are -- I'm hesitating because the licenses may differ between the two parties. One of them may have expired, one of them may still be in effect, I have to actually check that. The licenses are tied to specific patents though, your Honor. That's the issue. They're not tied to the product. They obtained a settlement of pending litigations.

THE COURT: Could I just see the language of the license?

MR. WEISS: I have copies I can hand out.

THE COURT: I don't want to read a thousand-page

encyclopedia, but can I just see the language you're talking about and the language he's talking about?

MR. CLEMONT: Your Honor, Actavis and Roxane have slightly different language.

THE COURT: Now, what's the language that I could, that would be helpful to focus on?

MR. CLEMONT: Your Honor, on behalf of Roxane I'm looking at Section 1.16B where it's talking about the licensed patents. Are you there?

THE COURT: I am there.

MR. CLEMONT: Okay. It says, what they're licensing are any United States patent application that claim priority to the Opana ER patents. Okay? That's very important. That claim priority. The Opana ER patents that are defined which is down on 1.20, they have a common priority to the two patents, the '122 and the '216 patents in suit here. So that license is a license --

THE COURT: Where is the language about product?

MR. CLEMONT: I'm not arguing product, your Honor. I'm arguing we have a patent under the license.

THE COURT: Let's go back to the other defendant. Where is the language about product?

MR. WEISS: Yes, your Honor. So, I'll sit so the microphone works better. I would draw your Honor's attention first to Section 4.1. This is on page 6 of 19.

THE COURT: Okay.

MR. WEISS: And you see 4.1A and I'm not going to purport to quote. I'm going to skip some of the things. But it says subject to the terms and conditions hereof, there's a royalty license and if you look in the center, it's there, to make, have made, offer to sell, sell, import and use the Opana ER generic products in the territory, etc. B has a covenant not to sue.

THE COURT: Wait a minute. Let's look at 4.1.

MR. BLACK: If you'll note, your Honor, in 4.1 it says that the license is under the asserted patent and that's all in caps.

MR. WEISS: We'll get to the --

MR. BLACK: Guess you don't want to talk about that.

MR. WEISS: I'll get there.

MR. BLACK: In the sixth line, only under the asserted patent, all in capitals, and that's a defined term on the first page of the agreement.

MR. WEISS: I haven't gotten to the rest of it yet.

THE COURT: Let's have one at a time, please.

MR. WEISS: If I could continue, your Honor.

THE COURT: Yes.

MR. WEISS: So 4.1 there's a license under the asserted patent to make, use, sell Opana ER product. 4.1B --

THE COURT: Wait a minute. 4.1 I still am not sure I

see the language you're talking about.

MR. WEISS: Okay, your Honor. So 4.1A, it's about five lines up from the bottom of the paragraph.

THE COURT: Okay. One, two, three, four -- I'm there.

MR. WEISS: Okay. Do you see where it says under the asserted patent during the licensed term --

THE COURT: Wait a minute. Under the asserted patent during the licensed term.

MR. WEISS: Right, to make, have made, offer to sell, sell, import and use the Opana ER generic product in the territory, and it goes on from there. So there's no question that what we have here is Opana ER generic product. The question is whether it's licensed under the patent that Endo is asserting. Now, Mr. Black points out correctly that 4.1A says asserted patent but 4.1B --

THE COURT: Okay.

MR. WEISS: During the covenant term, which is until everything runs, Endo and PennWest, that was the co-owner of some of these patents covenant not to sue Actavis or its affiliates for its infringement of or otherwise assert, and here we have a broader term, the Opana ER patents.

THE COURT: Yeah, okay.

MR. WEISS: And, again, based on the manufacture, use, import, sale, offer for sale of Opana ER products. So we have a license for one patent, we have a covenant not to sue with

respect to this defined term Opana ER patents for our product which is the Opana ER generic product.

Now, if you turn back, your Honor, to page 3 of the license agreement, we have some defined terms.

THE COURT: Okay.

MR. WEISS: The first full one is Opana ER generic product means any product that's marketed or sold under the Actavis ANDA. That's what we have here. Then we have Opana ER patents, which is what's covenant not to sue and that's broader. It says the asserted patents and U.S. patents 5128143 and then 5662993 and then 7276250. And any continuations, continuations in part or divisionals and any U.S. patents resulting from any reissue or re-examination. So this was not just patents in existence in 2009. This is continuations, continuations in part, divisionals and two of the patents at issue here which are the ones that Endo prosecuted itself and these are the '216 patent and the '122 patent are continuations of one of these patents. They're continuations of 7276250.

THE COURT: Can I interrupt? I thought it might, the way you described the license dealing with products I thought maybe there was some language here that was rather easily interpreted about products. Well, the language is not easily interpreted and at least to me sitting here, so I'm not going to pursue this any further.

What I'm wondering is would there be any advantage,

and there probably would not, but I'm going to ask it anyway, would there be any advantage, since there's not a jury here, would there be any advantage of having a hearing about the license issue, because if there is a license that allows the defendants to do what they say the license allows, then that's it. Obviously -- is there any advantage in splitting it up? There probably is not but I just ask the question,splitting up the license versus the validity issue.

MR. WEISS: I think, your Honor, there might be. The reason is, and again, I'm going to come back that your Honor is looking at this for the entirety now, obviously.

THE COURT: Of course.

MR. WEISS: The license part of our brief is about five pages. And the presumptions for a preliminary injunction that apply at trial are kind of reversed. So we cite a case, it's in footnote 13 of our brief, Display Tech v. Display Industries, it's a 2011 opinion from Judge Pauley dealing with a preliminary injunction in a patent case and the burden to get a preliminary injunction is on the plaintiff to produce countervailing evidence that the defense lacks substantial merit. So we're not talking about summary judgment here. We're talking about can they prove that the license defense lacks substantial merit.

Now, I don't see why this license agreement is not going to be subject to the parol evidence rule. It's an

integrated agreement. And as your Honor points out if the license issue is found to be a substantial issue then the preliminary injunction has to be denied. That is dispositive to the preliminary injunction.

I personally believe that it would be probably ripe for summary judgment also. But if your Honor wanted to take a quick response from Endo on this -- they only saw our papers this morning also -- maybe we could quickly put in a reply, your Honor could read the cases about implied licenses and estoppel that we cite, the Federal Circuit decision in TransCore and see what the Court thinks.

I don't think in terms of a hearing if your Honor means an evidentiary hearing, I don't think there's as I see it any witnesses to present or credibility issues. There's no dispute as to what the documents are. Now, if Endo would try to bring in somebody to say, well, what I had in mind was something different, again, whether that would negate a substantial issue I have no idea. It could get parol evidence problems. But we are potentially I think looking at an issue here that could not only be dispositive of a preliminary injunction but could be case dispositive. So it might be an extremely efficient way to proceed and I think it's something, depending on what your Honor's schedule is, that your Honor could look at a lot faster than trying to wade through a foot and a half of paper in regard to the dissolution

patents.

THE COURT: I'm going to ask you about timing, because we have in our court as the federal courts generally do September 30 and March 31 as dates when we all try to dispose of old motions as much as possible. And we work very hard for those dates. Obviously, I can do anything that I need to do. I can have a hearing in September or whatever, but what are the timing problems here, because, well, I'm just asking. What are the timing problems? I better ask Mr. Black.

MR. BLACK: Your Honor, from our perspective we're amenable to any schedule that works for the Court as long as we're not faced with a fait accomplis in the market that has launched.

THE COURT: As long as you're not faced with what?

MR. BLACK: As long as we're not faced with a change in the status quo, that is they've launched a generic product in the market before we have an opportunity to have our injunction motion decided. There's a practical issue with Roxane. We haven't seen any responsive papers from Roxane yet and Actavis' papers were filed this morning. But as far as setting a schedule to decide on whether their side has a summary judgment, entitlement to summary judgment on license, we would be fine with a procedure that went along that route so long as we weren't waiving our right to seek injunctive relief.

THE COURT: What are the plans of the defense?

MR. CLEMONT: Your Honor, for Roxane,we still have to submit papers. We would be happy to submit papers on this issue of license. We think it applies even more to Roxane than to Actavis.

THE COURT: I'm asking you about timing. What are your plans with your products?

MR. CLEMONT: Your Honor, as far as Roxane,we have told Endo that we would give them 30 days notice before we were to launch anything. We have not yet given them that notice. So there is no urgency with regard to Roxane at this point in time.

THE COURT: Actavis.

MR. WEISS: Your Honor, I hate to ask this, but there are a number of people who came into the courtroom after the parties. I don't know who they are and I'm reluctant to get into sensitive commercial information in open court in front of people who I don't know. I would certainly --

THE COURT: Well, wait a minute. I'll take care of that. We could just the lawyers and I step back to the robing room with the reporter and we'll have this on a sealed record for the moment.

(Pages 35 - 37 SEALED by order of the Court)